K123675

1. 510(k) SUMMARY

MAR 1 2013

510(K) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark
Phone/Fax/Email:	Office: (612) 302-4987 Mobile: (612) 968-9567 Fax: (612) 287-4138 Email: usbes@coloplast.com
Name of Contact Person:	Brian E. Schmidt Regulatory Affairs Manager
Address/Contact:	1601 West River Road N Minneapolis, MN 55411
Date Prepared:	January 3, 2013
Trade Name:	Re-Trace Ureteral Access Sheath Ureteral Access Sheath
Common Name:	Ureteral Access Sheath
Classification Name:	Endoscope and Accessories 21CFR section 876.1500 Gastroenterology-Urology Devices Class II
Product code:	FED

Legally Marketed Device To Which Your Firm Is Claiming Equivalence:

The **Re-Trace Ureteral Access Sheath 10/12 Ch/Fr & Ureteral Access Sheath** are substantially equivalent in performance, indication, design and materials to **Re-Trace Ureteral Access Sheath 12/14 Ch/Fr** from Coloplast A/S, cleared under Premarket notification # K102485.

Description of the Device:

The **Re-Trace Ureteral Access Sheath 10/12 Ch/Fr & Ureteral Access Sheath** are line extensions of the **Re-Trace Ureteral Access Sheath 12/14 Ch/Fr**. All these devices comprise the following components:

- Reinforced tube/sheath
- Introducer/dilator
- Connector
- Clip

The only design addition to the 10/12 Ch/Fr reinforced tube/sheath compared to the 12/14 Ch/Fr sheath is the presence of a reinforcing Stainless Steel ring at the distal tip.

For the **Ureteral Access Sheath**, the introducer/dilator also only has a guidewire entry eye at the distal tip compared with guidewire entry and exit eyes and three exit holes for fluid delivery on the **Re-Trace Ureteral Access Sheath** introducer/dilator.

Apart from these modifications, all the **Re-Trace Ureteral Access Sheath & Ureteral Access Sheath** range is very similar in design.

Intended Use of the Device:

To establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.

Predicate Device:

The **Re-Trace Ureteral Access Sheath 10/12 Ch/Fr & Ureteral Access Sheath** are substantially equivalent in performance, indication, design and materials to **Re-Trace Ureteral Access Sheath 12/14 Ch/Fr** from Coloplast A/S, cleared under Premarket notification # K102485.

Reference Device:

Regarding the proposed size range for **Re-Trace Access Sheath & Ureteral Access Sheath**, the Cook Flexor® Access Sheath from Cook Urological, Inc., cleared under Premarket notification #K043418, will be used as a reference device.

Summary and Conclusions from the Nonclinical Tests Submitted:

Product Performance testing comparing the subject device to the predicate device included the following tests/analysis: Sheath/ introducer/component break force testing, friction testing, kink resistance testing, injection testing, guidewire pullout force testing, packaging testing.

Biocompatibility testing was performed according to ISO 10993 on the **Re-Trace Ureteral Access Sheath**.

Conclusion

Substantial equivalence is supported by successful completion of the performance testing comparing **Re-Trace Ureteral Access Sheath 10/12 Ch/Fr & Ureteral Access Sheath** to the predicate device and the biocompatibility testing conducted on the **Re-Trace Ureteral Access Sheath**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 01, 2013

Coloplast A/S
Coloplast Corp.
% Mr. Brian E. Schmidt
Regulatory Affairs Manager
1601 West River Road North
MINNEAPOLIS MN 55411

Re: K123675
Trade/Device Name: Re-Trace Ureteral Access Sheath (Models ACXL10 and AXXL10) and Ureteral Access Sheath (Models ACXS12, AXXS12, ACXS10 AXXS10)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: November 27, 2012
Received: December 4, 2012

Dear Mr. Schmidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misb randing and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. **STATEMENT OF INDICATIONS FOR USE**

Indications for Use

510(k) Number (if known): K123675

Device Name: **Re-Trace Ureteral Access Sheath 10/12 Ch/Fr & Ureteral Access Sheath**

Indications for Use:

To establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.03.01 17:00:36 -05'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123675